10.0 EXECUTIVE SUMMARY

Company Name: Grifols Diagnostic Solutions Inc.

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Device Trade Name: Procleix Xpress® System

Device Common Name: Blood Pooling and Pipetting Instrument and Software

Classification Name: Software, Blood Bank, Stand Alone Products (21 CFR 864.9175)

Device Class: Class II

Product Code: 81MMH

Predicate Device:

Company Name: Chiron Corporation
4560 Horton Street,
Emeryville, CA 94608-2916

Device Name: Chiron CPT Pooling Software, Version 2.0.0.2

510 (k) #: **BK000049**

Date Cleared: 04 December 2001

10.1 Device Description:

The Procleix Xpress® System is a pooling and archiving instrument engineered to complement the Procleix portfolio of products. The Procleix Xpress System (Software and Pipettor) work together as follows:

- **Prior to pooling/archiving:** From within the Procleix Xpress Software, the operator selects a process that specifies the run parameters. After the process is selected, the software interface updates to display the correct arrangement of racks on the pipettor worktable.
- **During pooling/archiving:** The Procleix Xpress Pipettor scans each rack and tube on the Worktable, ensuring correct placement of all elements and establishing positive sample identification. Upon successful scanning, the instrument pipettes a predefined amount from each individual donor sample into a Master Pool Tube (MPT).
- **Following pooling/archiving:** The Procleix Xpress Software compiles pipetting data for each specimen pipetted and generates a Worklist file for the run, as well as an MPT file for each Master Pool created. On the Pipettor, the samples in each MPT are mixed by aspirating and dispensing approximately 800 µL three times.

The device provides a variety of features that simplify the pipetting tasks, including an air-based pipetting that does not require a priming-run. In addition, the device does not require weighing Master Pool Tubes (MPTs). There is no liquid waste disposal. The tips used with this device are compatible with Procleix Panther and Procleix Tigris systems. The device has a touchscreen, and provides visual and audible status alerts. Archiving and pooling configurations are modifiable. The device provides cybersecurity via a firewall.

10.2 Device Description – New and Existing Functionality:

10.2.1 Procleix Xpress System – New Functionality

The main improvement to Procleix Xpress System over the predicate is the removal of the gravimetrics process. The predicate pipettor is currently marketed for pooling plasma and serum samples to be processed with the Procleix systems and assays (such as Procleix Ultrio Assay, Procleix Ultrio Plus Assay). During pipetting, there is the potential for errors to occur. Errors may occur due to sample conditions (bubbles, clots, etc.) or as the result of hardware or software failure. Such errors could then potentially result in releasing a reactive sample as a false-negative, in a worst case scenario. In practice, instrument error rates are very small. Even so, systematic mitigations are currently performed to reduce this residual risk where possible. The current process to mitigate risk of a false negative in the predicate, is to perform manual gravimetric volume verification (correlated to pooling transfer of the predicate) and instrument error detection via liquid level detection.

The Procleix Xpress System has added features that improve sample surveillance, thus ensuring more accurate pipetting. Consequently, the improved sample surveillance provides mitigations for potential errors without the need for manual gravimetric volume verification. These mitigations were accomplished through hardware and software upgrades performing sample surveillance (error detection technology, including pressure monitored pipetting (PMP) with liquid level detection, and air based pipetting technology), as well dispense volume specifications that are at least as stringent as the predicate.

10.2.2 Device Description – Existing Functionality:

Intended Use / Indications for Use:

The Procleix® Xpress System (Software and Instrument) is intended to be used to create pools of human plasma or serum for in vitro diagnostic testing, such as blood screening tests for viral nucleic acids. The Procleix® Xpress System automatically transfers plasma or serum from individual samples into a single master pool tube, which may be used for further testing in Procleix® systems. The Procleix® Xpress System also collects barcode data from all tubes, racks, and archive plates used in a given pooling run, establishing positive specimen identification and Master Pool Tube (MPT) composition. In addition, the Procleix® Xpress System can be used to dispense human plasma or serum aliquots into an archive plate.

Note: “Procleix systems” refers to any equipment platform in the Procleix product line. Regulatory approvals and commercial availability vary by region.

10.3 Comparison to Predicate Devices (Chiron CPT Pooling Software, Version 2.0.0.2)

10.3.1 TABLE 1: Similarities

Features	Procleix Xpress System (Proposed Device)	Chiron CPT Pooling Software (Predicate Device) (Used in conjunction with TECAN GENESIS RSP 150/8 or 200/8 instrument)
Intended Use	Pooling Pipettor	Pooling Pipettor
Indications for Use	The Procleix Xpress® System (Software and Instrument) is intended to be used to create pools of human plasma or serum for in vitro diagnostic testing, such as blood screening tests for viral nucleic acids. The Procleix Xpress® System automatically transfers plasma or serum from individual samples into a single master pool tube, which may be used for further testing in Procleix® systems. The Procleix Xpress® System also collects barcode data from all tubes, racks, and archive plates used in a given pooling run, establishing positive specimen identification and Master Pool Tube (MPT) composition. In addition, the Procleix Xpress® System can be used to dispense human plasma or serum aliquots into an archive plate. Note: "Procleix systems" refers to any equipment platform in the Procleix product line. Regulatory approvals and commercial availability vary by region.	The PROCLEIX® CPT Pooling Software, used in conjunction with the TECAN GENESIS RSP 150/8 or 200/8 instrument, is intended to be used to create pools of human plasma for *in vitro* diagnostic testing, such as blood screening tests for viral nucleic acids. The combined instrument system automatically transfers plasma from individual samples into a single master pool tube, which may be used for further testing in the PROCLEIX® System or PROCLEIX® TIGRIS® System. The PROCLEIX CPT Pooling Software can also be used to dispense samples into an archive plate and generate a scan file that contains sample and Master Pool Tube barcode IDs.

Features	Procleix Xpress System (Proposed Device)	Chiron CPT Pooling Software (Predicate Device) (Used in conjunction with TECAN GENESIS RSP 150/8 or 200/8 instrument)
Liquid pipetting platform	Yes	Yes
Liquid level detection	Yes	Yes
Barcode sample tracking	Yes	Yes
Safety shield panels	Yes	Yes
External computer	Yes	Yes
Pools individual samples into one tube	Yes	Yes
Pooling Software	Yes	Yes
Multi pipetting	Yes 8 Channels	Yes 8 Channels
Clot detection	Yes	Yes
Uses Disposable tips	Yes	Yes
Hand held scanner	Yes	Yes
Archiving of Samples	Yes	Yes
Pooling Data Output	Yes, Pool File	Yes, Pool File
Access control	UserID/password credentials. Two users levels: User and Supervisor	UserID/password credentials. Two users levels: User and Supervisor
Target Population	Donated blood samples	Donated blood samples
LAN Connectivity	Yes	Yes
Error Message Concept	Yes	Yes
File Archiving	Yes	Yes

10.3.2 TABLE 2: Differences

Feature	Procleix Xpress System Pipettor (Proposed Device)	BK000049 (Predicate Device) Chiron CPT Pooling Software used in conjunction with TECAN GENESIS RSP 150/8 or 200/8 instrument
Pressure monitored pipetting	Yes	No
Air driven pipettor	Yes	No
Status notification lights	Yes	No
Audible alarm	Yes	No
Firewall Security device	Yes	No
Gravimetric confirmation required	Not Required	Required
Operating System	Windows 7	Windows XP

10.3.3 Similarities and Differences Between Procleix Xpress System and the Predicate Device

During pre-submission discussions begun by Grifols on October 26, 2012 (CRMTS 8736/PS001857), the FDA recommended the use of the Chiron CPT Pooling Software (used in conjunction with TECAN GENESIS RSP 150/8 or 200/8 instrument) as the predicate device, due to the close similarity to the functionality provided by the Procleix Xpress System. (NOTE: The pre-submission was filed under our previous legal entity name --- Novartis Vaccines and Diagnostics, Inc., prior to the sale of the diagnostics business of Novartis to Grifols.)

First, the intended uses of the two devices are equivalent. Second, the two devices have "the same technological characteristics," as there is no "significant change in the materials, design, energy source, or other features of the device from those of the predicate device."

The main improvement to Procleix Xpress System over the predicate is the removal of the Gravimetrics process. The predicate pipettor is currently marketed for pooling plasma and serum samples to be processed with the Procleix systems and assays (such as Procleix Ultrio Assay, Procleix Ultrio Plus Assay). During pipetting, there is the potential for errors to occur.

Errors may occur due to sample conditions (bubbles, clots, etc.) or as the result of hardware or software failure. Such errors could then potentially result in releasing a reactive sample as a false-negative, in a worst case scenario. In practice, instrument error rates are very small. Even so, systematic mitigations are currently performed to reduce this residual risk where possible. The current process to mitigate risk of a false negative in the predicate, is to perform manual gravimetric volume verification (correlated to pooling transfer of the predicate) and instrument error detection via liquid level detection.

The Procleix Xpress System has added features that improve sample surveillance, thus ensuring more accurate pipetting. Consequently, the improved sample surveillance provides mitigations for potential errors without the need for manual gravimetric volume verification. These mitigations were accomplished through hardware and software upgrades performing sample surveillance (error detection technology, including pressure monitored pipetting (PMP) with liquid level detection, and air based pipetting technology), as well dispense volume specifications that are at least as stringent as the predicate.

Verification and Validation activities for sample surveillance, maintenance of the system and the verification of target volume specifications, demonstrate reproducibly dispense of accurate volumes during the pooling process. In addition, any dispenses that do not meet dispense volume requirements are suitably detected by the sample surveillance capability of the Procleix Xpress System. The possibility of inaccurate dispenses have been suitably mitigated by the design of the Procleix Xpress System such that the gravimetrics process is not be necessary.

As demonstrated by the verification and validation reports included with this submission, the aforementioned improvements do “not raise different questions of safety and effectiveness and the device is as safe and effective as the legally marketed device (as defined in section 513(i)(1)(B) of the FD&C Act).”

Conclusion:

Both Procleix Xpress System and the predicate instrument are Blood Establishment computer software and hardware devices; and, both perform the same functionality within the

laboratory environment to create pools of human plasma or serum for in vitro diagnostic testing (specifically, for blood screening). Based on the foregoing, it is concluded that there is no significant difference between the basic functionality and the safety and effectiveness of the Procleix Xpress System and the named predicate device.

10.4 Summary of Performance Testing

The performance requirements of the Procleix Xpress System were documented in the PRD (CPT 4.0 Pooling/Archiving System Product Requirements Document - Grifols Document # 276388, included in **Appendix 2**). All performance requirements were verified as met during the design verification activities. The criteria for pipetting accuracy, cross contamination, false error rate, leakage, clot and bubble detection, and the study design, results and conclusions are summarized in section 18 and elaborated in documents included in **Appendices 8, 9 and 10**.

The comparability of pooling performance between Procleix Xpress System and CPT3/Genesis (Genesis) System was demonstrated through a multi-site Comparability Study as part of design validation, "Validation Report for CPT 4.0 Pooling/Archiving Integrated System"- Grifols Document #316203, included in **Appendix 9.**

Conclusion

Grifols Diagnostic Solutions has demonstrated through its evaluation and testing that the Procleix® Xpress System is substantially equivalent to the legally marketed Chiron CPT Pooling Software (used in conjunction with the TECAN GENESIS). A hazard analysis was performed and all hazards were mitigated. Like its predicate device, the Procleix Xpress System is safe and effective for its intended use.